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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

January 14, 1999

WARNING LETTER
CIN-WL 99-106

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Andrew Stutzman
4319 County Rd. 160
Kidron, Ohio 44654

Dear Mr. Stutzman:

The Food and Drug Administration (FDA) was informed by the USDA that tissue from a dairy cow identified with the back tag number: 31NW7847, and slaughtered on or around 8/28/98, was found to contain an illegal drug residue. The USDA laboratory's analytical report #394693, shows that the kidney tissue of the referenced animal contained 1.50 ppm Penicillin. The established tolerance for this drug in cows intended for slaughter as human food is: 0.05 ppm.

This cow was offered for slaughter as food in violation of Sections 402 (a)(2)(C) (ii), and 402 (a)(4) and Section 501 (a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). An investigation at your dairy operation conducted by our investigator on October 14, 1998, determined that this cow belonged to you.

A food is adulterated under Section 402 (a)(2)(C) (ii) of the Act, if it contains a new animal drug which is unsafe within the meaning of Section 512 and Section 402 (a)(4) if the food has been held under insanitary conditions whereby it may have been rendered injurious to health. As it applies in this instance, "insanitary conditions", refers to your lack of records for animals which you medicate. Consequently, you held an animal, likely to enter the food supply, under conditions so inadequate that a medicated animal bearing possibly harmful drug residues, was offered for sale for food.

A drug is adulterated under Section 501 (a)(5) if it is administered in a manner other than in accordance with the directions specified in the labeling, thereby making it unsafe within the meaning of Section 512(a)(1)(B). Therefore, you adulterated the drug by your failure to follow the recommended withholding time.

During our investigation, you told our investigator that the penicillin had been administered by your veterinarian. However, it remains important for you to realize that it is your responsibility to be aware of the medicated status of your animals, and to assure that animals with illegal residues are not offered for food.

The above is not intended to be an inclusive list of violations. For your reference, we have enclosed a booklet addressing residue prevention.

Please notify this office within fifteen (15) working days of the receipt of this letter of the specific steps that you have taken to correct the noted violations. Your response should include an explanation of each step being taken to prevent the recurrence of similar violations in future. If your corrective action can not be completed within 15 working days, please state the reason for the delay, and the time frame within which the necessary corrections will be completed.

Failure to promptly implement adequate corrections may result in further regulatory action such as seizure and/or injunction, without additional notice.

Your response should be directed to the U. S. Food and Drug Administration, Cincinnati District Office, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, ATTN: David C. Radle, Tissue Residue Monitor.

Sincerely,

Mary S. Womack
Acting District Director
Cincinnati District

Enclosure

Cc: [redacted]